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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Wortzman, Gordon, Gans, Patel

Serial No.: 09/864,083

Filed: May 23, 2001

Attorney Docket No.: 01-40076-US

COMPOSITIONS FOR THE TREATMENT OF PIGMENTATION DISORDERS AND METHODS FOR THEIR MANUFACTURE

APPEAL BRIEF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

The above-identified patent application comes before the United States Patent and Trademark Office Board of Appeals and Interferences from the Final Rejection of Claims 1-23 by the Examiner in an Official Action mailed January 23, 2004. Pursuant to the Notice of Appeal filed March 10, 2004 and the Petition for Four Months Extension of Time filed concurrently herewith, set forth below is the Appellant's Brief. Two additional copies of this Brief are enclosed. A check in the amount of One Hundred Sixty Five Dollars ($165.00) is enclosed in payment of the fee under 37 C.F.R. § 1.17(c).

The Commissioner is hereby authorized to charge any fees which may be required during the entire pendency of the appeal, or credit any overpayment, to Deposit Account 18-0586.

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I. Real Party in Interest:

The real party in interest in the above-captioned application is Medicis Pharmaceutical Corp. ("Appellant"), a corporation of the State of Delaware, and having a place of business at 8125 N. Hayden Road, Scottsdale, AZ 85258. The application has been assigned to Medicis Pharmaceutical Corp. by the inventors: Mitchell Wortzman, Philip Gordon, Eugene Gans and Bhiku Patel.

II. Related Appeals and Interferences:

There are no appeals or interferences known to Appellant or Appellant's legal representative which will directly affect or be directly affected by or have a bearing on the Board's decision in this present appeal.

III. Status of Claims:

Claims 1 to 23 are pending. Claims 24 to 116 were withdrawn. Claims 1 to 23 were finally rejected under 35 U.S.C. §103 as being unpatentable over U.S. Patent No. 5,932,612 ("Gordon"), in an Office Action mailed January 23, 2004. Claims 1 to 9 were finally rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 5,980,871 ("Lukenbach") in view of Gordon. Claims 1 to 23 are the subject of the present appeal.

IV. Status of Amendments:

No amendments have been filed subsequent to the Final Rejection.

V. Summary of the Invention:

As recited in independent claim 1, the present invention is directed to a composition comprising hydroquinone, and a cationic salt of acidic ascorbyl esters, with a pH of about 5.5 to about 8.0. Other dependant claims also cover narrower pH ranges. Some dependent claims also claim inorganic salts, e.g. without limitation, magnesium ascorbyl phosphate. Other

claims include amino acyl derivatives, e.g. without limitation, aminopropyl ascorbyl phosphate; or sodium ascorbyl phosphate.

The present invention is further described in other claims as additionally comprising a water-soluble antioxidant which may be a sulfite, including but not limited to sodium metabisulfite.

VI. Issues:

ISSUE 1

Whether claims 1-23 are nonobvious over Gordon.

ISSUE 2

Whether claims 1-9 are nonobvious over Lukenbach in view of Gordon.

VII. Grouping of Claims:

There are seven groups of claims. Group 1 consists of independent claim 1 and dependent claims 4-9. Group 2 consists of dependent claims 2 and 3. Group 3 consists of dependent claims 10 and 14-18. Group 4 consists of dependent claims 11-13. Group 5 consists of dependent claims 19-20. Group 6 consists of dependent claims 21-22. Group 7 consists of dependent claim 23.

VIII. Argument:

ISSUE 1

Whether claims 1-23 are nonobvious in view of Gordon.

The Examiner rejected claims 1 to 23 under 35 U.S.C. § 103 as being unpatentable over Gordon. Applicant traverses this rejection because the Examiner fails to establish a prima facie case of obviousness using Gordon with regards to the present invention. Applicant respectfully traverses these rejections for at least the following reasons.

Applicant agrees with the Examiner that "the pH of the said composition, a sodium metabisulfite ..., aminopropyl ascorbyl phosphate ...and sodium ascorbyl phosphate..." are not taught by Gordon.

35 U.S.C. 103(a) sets forth in part:

> [a] patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Hence, to establish a prima facie case of obviousness, three basic criteria must be met. First, the prior art reference (or references when combined) must teach or suggest all the claim limitations. Second there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Third, there must be a reasonable expectation of success. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

The Gordon reference fails to teach or suggest all the claim limitations in the present application. (See MPEP 706.02(j) (... the prior art reference (or references when combined) must teach or suggest all claim limitations.) The Examiner freely states:

> Gordon teaches most critical elements required by the instant claims **except** the pH of the said composition, a sodium metabisulfite (recited in claims 11-13 and 19-20), amino ascorbyl phosphate (recited in claims 21-22) and a

> sodium ascorbyl phosphate (recited in claim 23). [emphasis added].

Applicant respectfully submits Gordon does not teach or suggest the use of each of the claimed ingredients in a pH specific compound. Gordon does not teach or suggest "a pH of about 5.5 to about 8.0." (See Applicant's Claim 1) Since Gordon does not teach the claim limitations of Claim 1 of the present invention as stated hereinabove, Gordon cannot render obvious Claim 1 of the present Application.

In addition, Applicant asserts that dependent Claims 2-23 are likewise in a condition for allowance by virtue of their ultimate dependence on independent Claim 1.

The Examiner has not met the burden of establishing a prima facie case of obviousness using the Gordon reference by failing to provide express support for Examiner's assertion that Gordon provides some suggestion or motivation to substitute the "active agents" or modify the pH (See April 23, 2003 Office Action, p. 3). Examiner is required to provide express support from the art cited against Applicant, as opposed to merely stating that some suggestion or motivation exists or would be within the "skilled level of the artisan . . . absent evidence to the contrary." Id. See MPEP 2144.08.

Thus, the burden of proof is on the Examiner to show, by evidence, that the cited prior art provides the necessary suggestion or motivation to combine the cited references for a proper rejection under §103(a). Gordon not only fails to provide some suggestion or motivation for the substitution of "active agents" or the modification of pH, but Examiner's opinion of the ordinary skill in the art is insufficient to support a rejection under §103(a). Gordon does not teach "manufactur[ing] processes [which are] efficient (e.g. easy accessibility and cost reduction); and . . .pH [modifications that]... less[en] skin irritation... [and] reduce side effects" as suggestions

or motivations to modify Gordon into Applicant's claimed invention. (See April 23, 2003 Office Action, p. 4). Merely reciting that substitutions are "considered to be well within the skilled level of the artisan," (April 23, 2003 Office Action, p. 3) is insufficient evidence for an obviousness rejection; a mere assertion, unsubstantiated by evidence, cannot form the basis for a rejection of the claim. Applicant also invited the Examiner, if she was relying on facts within her personal knowledge, to provide an affidavit pursuant to 37 C.F.R. 1.104(d)(2) (Oct. 23, 2003 Request for Reconsideration, p. 5), but the Examiner failed to do so. Absent such evidence, Gordon does not teach each claim element and does not suggest modifications to achieve Applicant's claimed invention. The Examiner's burden has not been met and the rejection should be withdrawn.

Even *assuming arguendo* that the Examiner has met the burden of establishing a prima facie case of obviousness, Applicant has refuted the obviousness rejection. Conventional wisdom was to use a pH of 3.3 to 4.0 for stable compositions with 4% or less hydroquinone (the Food and Drug Administration permits only this amount), and Applicant's higher pH was not suggested in Gordon. Applicant provided three examples of U.S. patents (attached as Exhibit 1 hereto) in the Interview with the Examiner and the Interview Summary which teach that compositions containing four percent (4%) or less hydroquinone are stably prepared in a pH range of 3.3 – 4.0, in essence, teaching away from using a higher pH for stable hydroquinone compositions. See, e.g., Ex. 1, U.S. Patent No. 5,889,054, col. 7, lines 54-56 and col. 13, lines 19-21, U.S. Patent No. 5,962,526, col. 7, lines 49-51 and U.S. Patent No. 5,554,652, col. 7, lines 59-61. Therefore, one of ordinary skill in the art would not find it obvious to prepare a hydroquinone composition at the higher claimed pH because the higher pH would be thought to induce instability and decomposition.

Dependent claims

Several groups of dependent claims have additional grounds to be found non-obvious. Dependent claims 2 and 3 (Group 2) require a narrower pH limitation, which Gordon does not teach or suggest.

Dependent claims 11 to 13 (Group 4) and claims 19 to 20 (Group 5) require sodium metabisulfite. Gordon does not teach or suggest the addition of sodium metabisulfite. The Examiner even admitted this in the Office Action. Therefore, these claims are not obvious in light of Gordon.

Additional dependent claims 21-22 (Group 6) require an amino acyl derivative, which again, is not taught or suggested in Gordon. Dependent claim 23 (Group 7) also requires sodium ascorbyl phosphate. The Examiner admitted that "aminopropyl ascorbyl phosphate ... and sodium ascorbyl phosphate" are not taught by Gordon. Applicant also notes that nothing in Gordon suggests these substances. Therefore, these claims in Groups 6 and 7 are not obvious in light of Gordon.

Summary of Non-Obviousness in View of Gordon

The claims in Groups 1-7 have a pH limitation not taught nor suggested by Gordon. The claims in Group 2 have a narrow pH limitation, not taught or suggested by Gordon. The claims in Group 4 have a pH limitation and a requirement for sodium metabisulfite, which are not taught nor suggested by Gordon. The claims in Group 5 require a specified pH limitation, and sodium metabisulfite, none of which are taught or suggested by Gordon. The claims of Group 6 require a pH limitation and an amino acyl derivative, neither of which is taught or suggested by Gordon. Group 7's claim requires a pH limitation and sodium ascorbyl phosphate, neither of which is taught or suggested by Gordon. Therefore, the Examiner's burden has not been met for

any of the groups of claims, and in any case, one of ordinary skill in the art would not find Applicant's invention obvious over Gordon, and the rejection should be removed.

ISSUE 2

Whether claims 1-9 are nonobvious over Lukenbach in view of Gordon .

Claims 1 to 9 (Groups 1 and 2) were rejected under 35 U.S.C. § 103 by the Examiner as being unpatentable over Lukenbach in view of Gordon. The Examiner's use of Lukenbach, in combination with Gordon, fails to establish a prima facie case of obviousness in regards to the present invention. Applicant respectfully traverses these rejections for at least the following reasons.

Examiner admits:

> Applicant's claims differ [from those of Lukenbach et al] in that they require both ingredients together in one final product, and optionally with sodium metabisulfite.

(See April 23, 2004 Office Action, p. 4.)

Applicant respectfully submits Lukenbach et al in view of Gordon does not teach or suggest the use of the active agents, cationic salt of acidic ascorbyl esters and hydroquinone, together in one product with a pH in the range of about 5.5 to about 8.0. As discussed above, Gordon does not teach the specified pH range, while Lukenbach does not teach the combination of hydroquinone and cationic salts of acidic ascorbyl esters. In fact, Lukenbach teaches hydroquinone (without magnesium ascorbyl phosphate) compositions at about 7.5 pH (Lukenbach, Example 100C) and other compositions with magnesium ascorbyl phosphate (without hydroquinone) at about 7.5 pH (Lukenbach, Example 100B); each of these compositions were unstable and not aesthetically pleasing. A prima facie case of obviousness has not been established.

Additionally, Applicant has proven that there are unexpected results or advantages, which support the patentability of this invention. These unexpected results satisfy the nonobviousness requirements of § 103.

Unexpected advantages may be relied upon by an applicant to rebut a *prima facie* case of obviousness. See, for example, In re Soni, 54 F.3d 746, 34 U.S.P.Q. 2d 1684 (Fed. Cir. 1995); In re Chupp, 816 F.2d 643, 2 U.S.P.Q.2d 1437 (Fed. Cir. 1987); and In re Albrecht, 514 F.2d 1389, 185 U.S.P.Q. 585 (CCPA 1975). In each case, the applicant relied upon unexpected advantages to rebut a *prima facie* case of obviousness. In each case, the courts found the claims to be patentable.

The stable, non-discoloration feature of the invention sufficiently establishes that an unexpected result is exhibited by the claimed composition, thereby meeting the statutory requirement of nonobviousness of 35 U.S.C. §103. See Supplemental Declaration by Philip J. Gordon (filed December 10, 2003), at Exhibit A (attached hereto as Exhibit 3).

Additionally, neither Lukenbach nor Gordon addresses additional problems solved by the present invention, including the discoloring and/or oxidation of the Applicant's composition. Applicant submits that the stability of Applicant's composition, i.e. the combination of the claimed compounds in the specified pH range, is a result unexpected by those skilled in the art. MPEP § 716.05(b) states:

> Evidence of unexpected properties may be in the form of a direct or indirect comparison of the claimed invention with the closest prior art which is commensurate in scope with the claims. See In re Boesch, 617 F.2d 272, 205 U.S.P.Q. 215 (CCPA 1980).

Applicant respectfully submits Lukenbach in conjunction with Gordon, fails to teach the cosmetically acceptable combination of the active agents at the given pH, a problem addressed

by the present invention. As stated in the attached Declaration by Philip J. Gordon[1] ("Gordon Declaration") and Supplemental Declaration (attached as Exhibits 2 and 3), laboratory preparations of example compositions, prepared according to Lukenbach, separately containing magnesium ascorbyl phosphate and hydroquinone, both at a pH of 7.5, do not present viable cosmetic formulations. Specifically, example 100B of Lukenbach, containing magnesium ascorbyl phosphate, began to brown and separate within days after mixing and additionally showed flocculation after a mere two weeks. (see Gordon Declaration, paragraph 4 and Exhibit A). While example 100C also discolored within days of mixing, and further exhibited signs of hydroquinone degradation within the first two weeks after mixing. (See Gordon Declaration, paragraphs 6 and 7and Exhibit B).

Cosmetic formulations must be stable and aesthetically acceptable. As seen in the photograph at Exhibit A of the Gordon Declaration, Lukenbach Example 100B is brown and not aesthetically pleasing. Exhibit B of the Gordon Declaration is a photograph of Lukenbach Example 100C, which is discolored, separated and not aesthetically pleasing either. Neither example 100B nor 100C in Lukenbach were cosmetically or aesthetically acceptable and showed degradation of the actives. This instability and unacceptability teaches away from combining hydroquinone and magnesium ascorbyl phosphate at a pH of 7.5. One of ordinary skill in the art would not expect the combination of the active agents in these unstable formulations to result in a stable, cosmetically pleasing formulation. Thus, as compared to Lukenbach's embodiments, the stability and resulting pleasing aesthetics of the present invention are unexpected in the applicant's invention and is not rendered obvious by Lukenbach and Gordon.

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1 Philip J. Gordon, an inventor on the present application, is not Benjamin Gordon from the Gordon reference (U.S. Patent No. 5,932,612) cited by the Examiner.

From the Lukenbach examples and the pH known for hydroquinone stable compositions (see Exhibit 1), one of ordinary skill in the art would never try to prepare Gordon at Applicant's specified pH range. Lukenbach therefore teaches away, or at a minimum lacks a suggestion, to combine with Gordon to create Applicant's invention.

The Examiner merely asserts that Lukenbach could be combined with Gordon. Mere assertions by the Examiner are not sufficient to establish a prima facie case of obviousness. Even if a naked assertion by the Examiner that it would be "obvious to combine two compositions each of which is taught by prior art to be useful for the same purpose," (January 23, 2004 Office Action, p. 6) could justify an initial rejection, that rejection must fail when the assertion is rebutted by actual evidence, such as seen here and referenced in the Gordon Declaration. Therefore, the Examiner has not met his burden.

The Examiner argues that the Gordon Declaration was not persuasive because "evidence of unexpected properties may be in the form of a direct or indirect comparison of the claimed invention with the closest prior art....." (*See In re Boesch*, 617 F.2d 272, 205 U.S.P.Q. 215 (CCPA 1980)) (January 23, 2004 Office Action, p. 7) However, Applicant has done this very thing. Lukenbach teaches hydroquinone or magnesium ascorbyl phosphate compositions at 7.5 pH. Since Lukenbach's examples are the closest prior art to Applicant's invention and they are unstable and cosmetically unappealing, Applicant's invention has an unexpected advantage.

Applicant did not compare the invention to the Gordon composition because, by the Examiner's admission, it is missing elements of the Applicant's claimed invention. Therefore, Applicant tested by comparison to the closest prior art, i.e. Lukenbach. The unexpected results of stability and cosmetically attractiveness overcome any obviousness rejection. While

Applicant does not believe such testing is necessary, Applicant is willing to do this experimentation on remand at the Board's suggestion.

Since Lukenbach fails as a reference under 35 U.S.C. §103 as stated hereinabove, Lukenbach cannot render obvious Claims 1 to 9 (Groups 1 and 2) of the present Application because it does not teach or suggest hydroquinone and magnesium ascorbyl phosphate together. Since one of ordinary skill in the art would not use Lukenbach to modify Gordon's pH, Lukenbach and Gordon in combination do not render claims 1 to 9 obvious.

Consequently, Applicant traverses the 35 U.S.C. §103(a) rejections and respectfully requests their reconsideration and removal.

CONCLUSION

In view of the foregoing discussion, it is respectfully submitted that the Examiner's rejections of claims 1-23 (Groups 1 to 7) are improper and should be reversed by the Board.

Express Mail Label No. EV 481406027 US Date of Deposit August 20 , 2004 I hereby certify that this paper, and the papers and/or fees referred to herein as transmitted, submitted or enclosed, are being deposited with the U.S. Postal Service "Express Mail Post Office to Addressee" on the date indicated above and is addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 Name: Elaine Weisbecker Signature Elaine Weisbecker	Respectfully submitted, **REED SMITH LLP** Maryellen Feehery Registration No.: 44,677 William J. McNichol, Jr. Registration No. 31,179 2500 One Liberty Place 1650 Market Street Philadelphia, PA 19103-7301 (215) 241-7988 Attorneys for Applicant

IX. APPENDIX

1. (original) A composition for the treatment of pigmentation disorders comprising:

   hydroquinone; and

   a cationic salt of acidic ascorbyl esters,

   said composition having a pH of about 5.5 to about 8.0.

2. (original) The composition of claim 1 wherein the pH is about 5.5 to about 7.5.

3. (original) The composition of claim 1 wherein the pH is about 6.0 to about 7.5.

4. (original) The composition of claim 1 wherein the hydroquinone is present in about 1 to about 12 %.

5. (original) The composition of claim 1 wherein the hydroquinone is present in about 2 to about 10 %.

6. (original) The composition of claim 1 wherein the hydroquinone is present in about 2 to about 8 %.

7. (original) The composition of claim 1 wherein the hydroquinone is present in about 3 to about 4 %.

8. (original) The composition of claim 1 wherein the hydroquinone is present in about 4%.

9. (original) The composition of claim 1 further comprising a water-soluble antioxidant.

10. (original) The composition of claim 9 wherein the antioxidant comprises a sulfite.

11. (original) The composition of claim 9 wherein the antioxidant comprises sodium metabisulfite.

12. (original) The composition of claim 11 wherein the sodium metabisulfite is present in at least about 0.05%.

13. (original) The composition of claim 11 wherein the sodium metabisulfite is present at about 0.05% to about 0.5%.

14. (original) The composition of claim 1 wherein the cationic salt comprises an inorganic salt.

15. (original) The composition of claim 1 wherein the cationic salt comprises magnesium ascorbyl phosphate.

16. (original) The composition of claim 15 wherein the magnesium ascorbyl phosphate is present in at least about 0.1%.

17. (original) The composition of claim 15 wherein the magnesium ascorbyl phosphate is present at about 0.25 to about 3%.

18. (original) The composition of claim 15 wherein the magnesium ascorbyl phosphate is present at about 0.25 to about 1%.

19. (original) The composition of claim 9 wherein the antioxidant comprises sodium metabisulfite and the cationic salt comprises magnesium ascorbyl phosphate.

20. (original) The composition of claim 19 wherein the sodium metabisulfite is present in at least about 0.05% and the magnesium ascorbyl phosphate is present in at least about 0.5%.

21. (original) The composition of claim 1 wherein the cationic salt comprises an amino acyl derivative.

22. (original) The composition of claim 21 wherein the cationic salt comprises aminopropyl ascorbyl phosphate.

23. (original) The composition of claim 1 wherein the cationic salt comprises a sodium ascorbyl phosphate.

Claims 24-116 (withdrawn)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Wortzman, et al

Serial No. 09/864,083

Filed: May 23, 2001

Art Unit: 1614

Examiner: Vickie Y. Kim

Attorney Docket No.: 01-40076-US

COMPOSITIONS FOR THE TREATMENT OF PIGMENTATION DISORDERS AND METHODS FOR THEIR MANUFACTURE

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

DECLARATION

1. I, Philip J. Gordon, am a named inventor of the above-referenced patent application. I am additionally the President of Concept Laboratories located at 680 North Glenville Drive, Richardson, Texas.

2. My laboratory employee prepared samples of Examples 100B and 100C as described in United States Patent No. 5,980,871. Both samples were prepared to total 500 grams and were adjusted to reach a pH of 7.5 in accordance with the procedure within the aforementioned patent.

3. Example 100B of United States Patent No. 5,980,871, which included magnesium ascorbyl phosphate, when prepared in accordance with the instructions provided by the patent, resulted in a white/off white, low viscosity lotion that appeared to be aerated.

4. The prepared samples of Example 100B were placed in a stability oven at various temperatures which produced the following stability results:

Temperature	Start Date	End Date	Comments
45°C	8/27/03	9/11/03	Sample browning and separating at surface.
40°C	8/27/03	9/11/03	Sample browning at surface.
45°C	8/27/03	9/17/03	Separation, flocculation and browning at surface.
40°C	8/27/03	9/17/03	Separation, flocculation and browning at surface.

5. In my opinion, Example 100B of United States Patent No. 5,980,871, when prepared in accordance with the instructions provided by the patent, does not represent a viable cosmetic formulation due to its discoloration, separation and flocculation at 40°C after only two weeks which indicates an unstable formulation (See photograph, attached as Exhibit A).

6. Example 100C of United States Patent No. 5,980,871, which included hydroquinone, when prepared in accordance with the instructions provided by the patent, resulted in a reddish/brown, medium viscosity lotion that appeared to be aerated.

7. The prepared samples of Example 100C were placed in a stability oven at various temperatures which produced the following stability results:

Temperature	Start Date	End Date	Comments
45°C	8/27/03	9/11/03	Sample graying at surface.
40°C	8/27/03	9/11/03	Sample graying at surface.
45°C	8/27/03	9/17/03	Sample graying at surface.
40°C	8/27/03	9/17/03	Sample graying at surface.

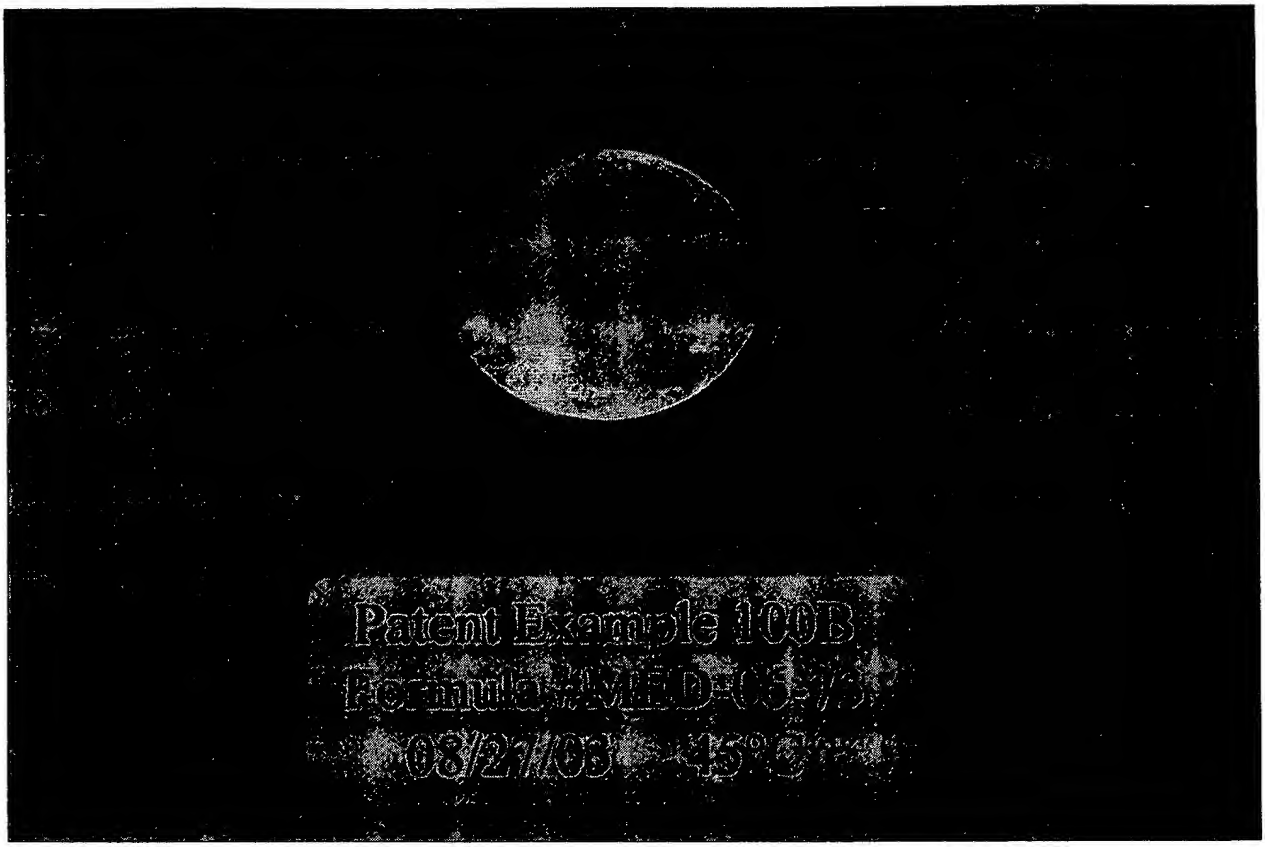
8. In my opinion, Example 100C of United States Patent No. 5,980,871, when prepared in accordance with the instructions provided by the patent, suggests that the hydroquinone rapidly degrades due to the high pH (7.5) of the formula. Example 100C appears to be fluffy and not smooth. Further, Example 100C is not a good cosmetic emulsion due to the color instability after two weeks at 40°C (See photograph, attached as Exhibit B), further having an initial color of brown, which may be due to hydroquinone degradation.

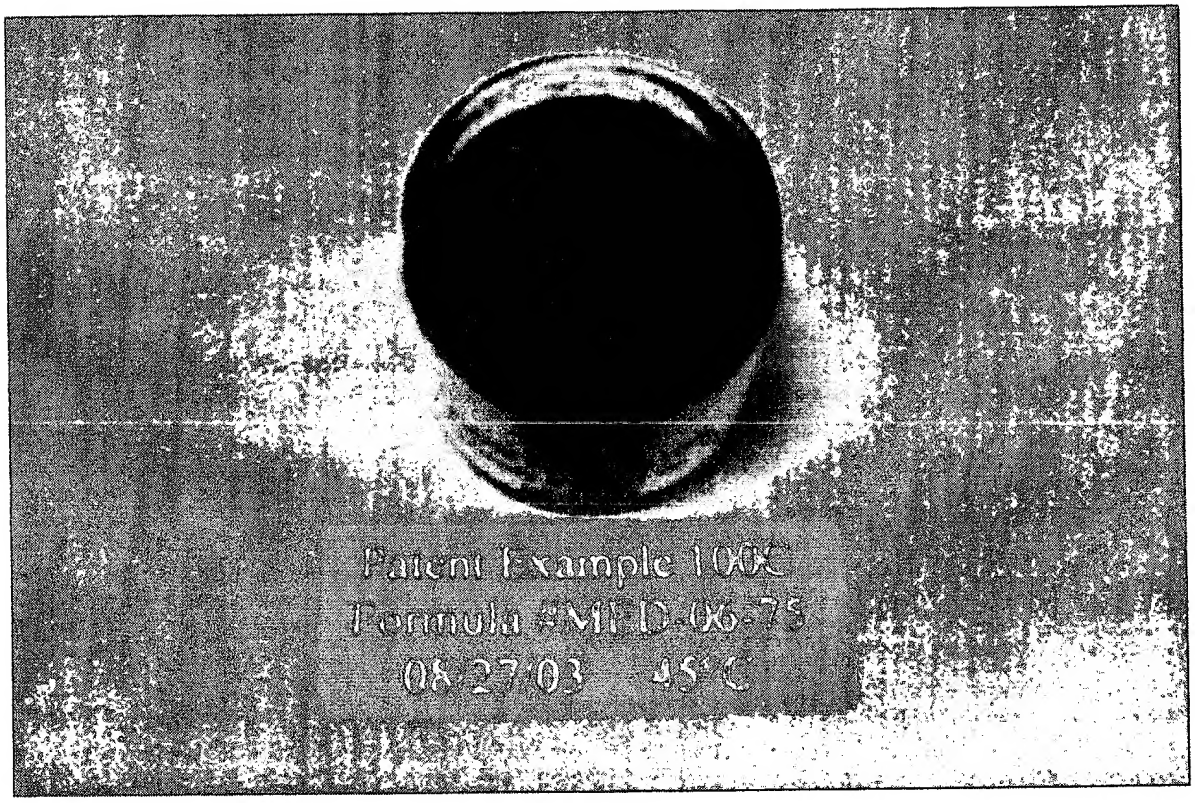
I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Respectfully Submitted,

Dated: 10/23/03

Philip J. Gordon


Patent Example 100B


Patent Example 100C
Formula #MID-06-75
08-27-03 45°C

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Wortzman, et al

Serial No. 09/864,083

Filed: May 23, 2001

Art Unit: 1614

Examiner: Vickie Y. Kim

Attorney Docket No.: 01-40076-US

COMPOSITIONS FOR THE TREATMENT OF PIGMENTATION DISORDERS AND METHODS FOR THEIR MANUFACTURE

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

SUPPLEMENTAL DECLARATION

1. I, Philip J. Gordon, am a named inventor of the above-referenced patent application. I am additionally the President of Concept Laboratories located at 680 North Glenville Drive, Richardson, Texas.

2. My laboratory employee prepared a sample of an embodiment of the invention described in the above identified United States Patent Application. The sample was prepared to total 500 grams and was adjusted to reach a pH of about 5.70-5.80 in accordance with the procedure within the aforementioned application.

3. The prepared sample was placed in a stability oven at various temperatures which produced the following stability results:

Temperature	Start Date	End Date	Comments
45°C	8/27/03	9/11/03	Product appears white and stable.
40°C	8/27/03	9/11/03	Product appears white and stable.
45°C	8/27/03	9/17/03	Product appears white and stable.
40°C	8/27/03	9/17/03	Product appears white and stable.

4. In my opinion, the prepared embodiment of United States Patent Application No. 09/864,083, when prepared in accordance with the instructions provided by the application, appears to represent a viable cosmetic formulation due to it not discoloring, indicating a stable formulation (See photograph, attached as Exhibit A).

5. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Respectfully Submitted,

Dated: 12/10/03

Philip J. Gordon

Philip J. Gordon